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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,722	05/16/2005	Evy Reitan	770033.401USPC	9705
500 7590 07/24/2007 SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104			EXAMINER WOOLWINE, SAMUEL C	
			ART UNIT 1637	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,722	Applicant(s) REITAN ET AL.	
	Examiner Samuel Woolwine	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/1/2004-5/10/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-15, in the reply filed on 5/10/2007 is acknowledged. The traversal is on the ground(s) that "the novel and inventive feature that links the method and kit claims together is the use of NH_4^+ or NH_3 in combination with a chaotrope and a nucleic acid binding solid phase in nucleic acid isolation" (page 6, paragraph 6 of the response). This is not found persuasive because such a feature is found in the prior art, as detailed in the rejection over Kuroita et al (USPN 5,990,302) below.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/10/2007.

With regard to the election of species requirement made in the previous Office action (OA 11/13/2006), this requirement is withdrawn. Claims 1-15 are rejoined.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the background shading of the graph in figure 1 obstructs what is

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being shown in the figure (see for example the publication of the instant application, US 2005/0214765 A1). Applicant is advised to submit a new drawing without background shading. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Replacement Drawing Sheets

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

Annotated Drawing Sheets

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

Timing of Corrections

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Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

Information Disclosure Statement

Reference WO 03/040603 A1 listed on the IDS of 5/10/2007 has been considered only with regard to the abstract, as there was no translation provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 (and by dependency claims 2-15) recite "providing a source of NH_4^+ or NH_3 " in step (c), but also recites "a liquid phase comprising the chaotrope and the NH_4^+ or NH_3 " in step (d). According to paragraph [0027] of the published instant application (US 2005/0214765 A1), "source of NH_4^+ or NH_3 is typically an ammonia solution although other possible sources include those capable of generating ammonia by a chemical reaction or transformation". Therefore, it is not clear whether the NH_4^+ or NH_3 recited in step (d) of claim 1 is limited to NH_4^+ or NH_3 *per se*, or whether it also includes a "source of NH_4^+ or NH_3 ", such as urea, which is a common chaotropic agent (see instant claim 11). Therefore the metes and bounds

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of the claims are not clear. Claim 14, which specifies that the source of NH_4^+ or NH_3 is a solution of ammonia, clarifies the issue, but only for that claim. For the remaining claims, for purposes of examination over the prior art, the examiner will assume that the NH_4^+ or NH_3 recited in step (d) of claim 1 is limited to NH_4^+ or NH_3 *per se*.

Claims 7-12 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7 and 9, and by dependency claims 8 and 10, respectively, recite "wherein the nucleic acid...". It cannot be determined whether this refers to the nucleic acid to be isolated, or to the nucleic acid contained in the sample (see claim 1 preamble). That is to say, a "nucleic acid-containing sample" could contain nucleic acid in addition to the particular nucleic acid that is to be extracted. For purposes of examination of claims 7-10 over the prior art, both interpretations will be considered (i.e. the nucleic acid is the nucleic acid to be isolated, or the nucleic acid is the nucleic acid contained in the sample).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuroita et al (USPN 5,990,302) as evidenced by Alleman (Free Ammonia-Nitrogen Calculator &

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Information [online], 24 December 1998, [retrieved on July 18, 2007], retrieved from the Internet: <cobweb.ecn.purdue.edu/~piwc/w3-research/free-ammonia/nh3.html>).

With regard to claim 1, Kuroita teaches:

A process for isolating nucleic acid from a nucleic acid-containing sample

(column 2, lines 51-52: "an isolation method of ribonucleic acid"),

which comprises: (a) providing a chaotrope (column 2, lines 53-56: "mixing a sample containing a ribonucleic acid, an acidic solution containing a lithium salt and a chaotropic agent and a nucleic acid-binding carrier, to adsorb the ribonucleic acid onto said carrier");

(b) providing a nucleic acid binding solid phase capable of binding nucleic acid in the presence of the chaotrope (column 2, lines 53-56: "nucleic acid-binding carrier");

(c) providing a source of NH_4^+ or NH_3 (Kuroita teaches examples of a chaotropic agents to be used in his invention including ammonium perchlorate and ammonium (iso)thiocyanate; column 4, lines 23-26: "Examples of the chaotropic agent to be used in the present invention include a compound selected from the group consisting of guanidine salt, urea, iodide, perchlorate and (iso)thiocyanate"; column 4, lines 37-41: "examples of perchlorate include sodium perchlorate, potassium perchlorate, lithium perchlorate and ammonium perchlorate... (iso)thiocyanate is exemplified by sodium (iso)thiocyanate, potassium (iso)thiocyanate and ammonium (iso)thiocyanate");

(d) contacting the sample with the nucleic acid binding solid phase in the presence of a liquid phase comprising the chaotrope and the NH_4^+ or NH_3 (column 2, lines 53-56: "mixing a sample containing a ribonucleic acid, an acidic solution containing

a lithium salt and a chaotropic agent and a nucleic acid-binding carrier, to adsorb the ribonucleic acid onto said carrier”);

and (e) optionally separating the solid phase with the nucleic acid bound thereto from the liquid phase (column 2, line 60: “eluting the ribonucleic acid from said carrier”).

With regard to claim 2, Kuroita teaches eluting (column 2, line 60: “eluting the ribonucleic acid from said carrier”).

With regard to claims 3 and 4, Kuroita teaches biological samples, including cellular samples (column 2, lines 45-46: “a method comprising dissolution of a biological material such as cells”).

With regard to claim 5, Kuroita teaches lysis (i.e. “dissolution”; column 2, lines 45-46: “a method comprising dissolution of a biological material such as cells”).

With regard to claim 6, Kuroita teaches examples of chaotropic agents such as ammonium perchlorate and ammonium (iso)thiocyanate (see discussion above).

Kuroita also teaches at column 2, lines 45-47 (with emphasis provided): “dissolution of a biological material such as cells in an acidic solution containing a lithium salt and a chaotropic agent”. Therefore, it follows that the ammonium (NH_4^+) is present during the lysis (“dissolution”) step.

With regard to claims 7 and 8, Kuroita describes a comparison between his method and a prior art method (column 8, lines 36-59), and states: “As is evident from FIG. 1, the ribonucleic acid (rRNA) obtained by the method of the present invention showed a greater yield than the ribonucleic acid obtained by the method of Boom et al., and less contamination of deoxyribonucleic acid”. Therefore, even though Kuroita

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regarded the genomic DNA (column 8, lines 47-50) as a contaminant, his method nonetheless isolated genomic DNA (which in the case of K562 cells, which is the sample type used in that experiment, is double-stranded (ds) DNA, since K562 cells are a human CML cell line (see column 7, lines 39-40)).

Furthermore, with regard to claims 7-10, since Kuroita practiced his method with human cells (K562 cells; see column 7, lines 39-40), and since "the nucleic acid" referred to in claims 7-10 can be interpreted as the nucleic acids contained in the sample (see discussion under the rejection of claims 7-10 under 35 U.S.C. 112, 2nd paragraph above), Kuroita anticipates claims 7-10 as human cells would comprise double-stranded DNA (i.e. genomic DNA), as well as rRNA, mRNA and total RNA.

With regard to claims 9 and 10, Kuroita clearly shows his method isolates rRNA (column 8, lines 36-59: "As is evident from FIG. 1, the ribonucleic acid (rRNA) obtained by the method of the present invention..."). Furthermore, Kuroita amplified mRNA obtained by his method (column 8, lines 60-61).

With regard to claim 11, Kuroita teaches all these types of chaotropes (see column 4, lines 20-26).

With regard to claims 12 and 13, Kuroita teaches magnetic silica particles (column 7, line 60).

With regard to claim 14, Kuroita teaches a solution comprising ammonium (column 4, lines 23-26: "ammonium perchlorate", "ammonium (iso)thiocyanate"). Any aqueous solution of free ammonia (NH_3) will inherently also contain some ammonium ion (NH_4^+) and vice versa, since these two species exist in chemical equilibrium.

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Evidence to support this assertion is found in Free Ammonia-Nitrogen Calculator & Information, by James Alleman, who states: "Free ammonia ($\text{NH}_3\text{-N}$) and ionized-ammonia ($\text{NH}_4^+\text{-N}$) represent two forms of reduced inorganic nitrogen which exist in equilibrium depending upon the pH and temperature of the waters in which they are found" (first sentence).

With regard to claim 15, Kuroita teaches chaotropic agents such as ammonium perchlorate and ammonium (iso)thiocyanate (column 4, lines 35-41). Therefore, the "source of NH_4^+ " and the chaotrope are provided together as a solution.

Claims 1, 3-5, 7, 8, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hewitt (EP 0261955 A2, published 03/30/1988) as evidenced by Alleman (Free Ammonia-Nitrogen Calculator & Information [online], 24 December 1998, [retrieved on July 18, 2007], retrieved from the Internet: <cobweb.ecn.purdue.edu/~piwc/w3-research/free-ammonia/nh3.html>).

With regard to claim 1, Hewitt teaches:

A process for isolating nucleic acid from a nucleic acid-containing sample (page 3, lines 10-20: "preparing DNA bound to a support"),

which comprises: (a) providing a chaotrope (page 3, lines 10-20, step (E): "chaotropic agent");

(b) providing a nucleic acid binding solid phase capable of binding nucleic acid in the presence of the chaotrope (page 3, lines 10-20, step (F): "support");

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(c) providing a source of NH_4^+ or NH_3 (page 5, lines 3-12; Hewitt teaches a preferred chaotropic agent is ammonium acetate);

(d) contacting the sample with the nucleic acid binding solid phase in the presence of a liquid phase comprising the chaotrope and the NH_4^+ or NH_3 (page 3, lines 10-20, step (F));

and (e) optionally separating the solid phase with the nucleic acid bound thereto from the liquid phase (since this limitation is optional, Hewitt need not teach this limitation).

With regard to claims 3 and 4, Hewitt teaches a biological sample, including cells (page 3, lines 10-20, step (A): "source organisms"; page 3, lines 23-25: "cells").

With regard to claim 5, Hewitt teaches a lysis step (page 3, lines 10-20, step (B): "treating said organisms with at least one lytic enzyme").

With regard to claims 7-8, Hewitt teaches ds DNA (page 3, line 11: "A method of preparing DNA..."; Hewitt teaches the cells may be of "mammalian or bacterial origin" (page 3, line 25) and thus the DNA would be double-stranded). However, Hewitt also teaches that the DNA bound to the support as a result of his method is rendered single stranded (page 3, lines 27-28). Thus the disclosure of Hewitt can also be construed to meet the limitation of "ss DNA" in claim 8.

With regard to claim 14, Hewitt teaches a solution of ammonium acetate (page 5, lines 3-12. Any aqueous solution of free ammonia (NH_3) will inherently also contain some ammonium ion (NH_4^+) and vice versa, since these two species exist in chemical equilibrium. Evidence to support this assertion is found in Free Ammonia-Nitrogen

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Calculator & Information, by James Alleman, who states: "Free ammonia (NH₃-N) and ionized-ammonia (NH₄⁺-N) represent two forms of reduced inorganic nitrogen which exist in equilibrium depending upon the pH and temperature of the waters in which they are found" (first sentence).

With regard to claim 15, Hewitt teaches a chaotropic agent and a source of ammonium that are one in the same (page 5, lines 3-12: "ammonium acetate").

Therefore, the source of ammonium and the chaotropic agent are provided together as a solution.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hewitt (EP 0261955 A2, published 03/30/1988).

With regard to claim 11, Hewitt teaches:

A process for isolating nucleic acid from a nucleic acid-containing sample (page 3, lines 10-20: "preparing DNA bound to a support"),

which comprises: (a) providing a chaotrope (page 3, lines 10-20, step (E): "chaotropic agent");

(b) providing a nucleic acid binding solid phase capable of binding nucleic acid in the presence of the chaotrope (page 3, lines 10-20, step (F): "support");

(c) providing a source of NH_4^+ or NH_3 (page 5, lines 3-12; Hewitt teaches a preferred chaotropic agent is ammonium acetate);

(d) contacting the sample with the nucleic acid binding solid phase in the presence of a liquid phase comprising the chaotrope and the NH_4^+ or NH_3 (page 3, lines 10-20, step (F));

and (e) optionally separating the solid phase with the nucleic acid bound thereto from the liquid phase (since this limitation is optional, Hewitt need not teach this limitation).

Hewitt also teaches the following chaotropic agents: ammonium acetate, sodium perchlorate, sodium iodide, and sodium trifluoroacetate (page 5, lines 3-12). Since the rejection relies on Hewitt's teaching of ammonium acetate as the chaotropic agent, Hewitt cannot be said to anticipate claim 11, which requires the chaotrope to comprise a guanidinium salt, urea, an iodide, chlorate, perchlorate or (iso)thiocyanate.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to combine the ammonium acetate with any of the other chaotropes taught by Hewitt (including sodium iodide or sodium perchlorate, thus resulting in the claimed invention), because Hewitt expressly suggests mixtures of chaotropic agents (page 5, line 3: "The sample so processed is further treated with a chaotropic agent or a mixture of chaotropic agents..."). Since Hewitt lists only 4 specific chaotropic agents, one of ordinary skill in the art would immediately have envisaged mixtures of these agents. There are 6 possible mixtures of two, 4 possible mixtures of 3, and only 1 possible mixture of four, of the four chaotropic agents listed by Hewitt. Of these 11 possible mixtures, 6 would meet the limitation of claim 11 in comprising ammonium acetate and either sodium iodide or sodium perchlorate.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

scw

/Young J. Kim/
Primary Examiner
Art Unit 1637
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